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Attorneys for Plaintiff

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA,	)	CR No. 08-0164 MHP
	)	
Plaintiff,	)	STIPULATION AND [PROPOSED]
	)	SUPERSEDING PROTECTIVE ORDER
v.	)	
	)	
W. SCOTT HARKONEN,	)	
	)	
Defendant.	)	

Defendant W. Scott Harkonen is charged with violations of Title 18, United States Code, Sections 1343 and 2 – wire fraud and aiding, and Title 21, United States Code, Sections 21 U.S.C. §§ 331(k), 333(a)(2) and 352(a) – doing acts, with intent to defraud and mislead, resulting in drugs being misbranded while held for sale following shipment in interstate commerce. More

1 specifically, the drug at issue is Actimmune and the conduct at issue took place when the  
2 Defendant was employed by InterMune, Inc.

3 The Court has previously issued a protective order relating to discovery containing certain  
4 individually identifiable health information (defined as health information that is connected to a  
5 patient's name, address, Social Security number or other identifying number, including HIC  
6 number) on 23, 2008.

7 At this time, the parties jointly seek a superseding protective order to include not only  
8 discovery containing certain individually identifiable health information but also confidential  
9 business, financial, proprietary, or other confidential information of third parties, including  
10 InterMune, Inc., submitted to the United States Food and Drug Administration ("FDA") related  
11 to drug applications and other filings and communications.

12 To expedite the production of discovery material and to adequately protect the  
13 information provided health information and information provided to the FDA, the parties agree  
14 and stipulate that materials containing financial, proprietary, or other confidential information of  
15 a third party, InterMune, Inc., submitted to or in the possession of the United States Food and  
16 Drug Administration ("FDA") or any material containing certain individually identifiable health  
17 information will be handled in accordance with the conditions set forth below. In order to protect  
18 the confidentiality of this information, and with the stipulation of the parties, the government  
19 asks the Court to enter the following protective order:

20 1. The parties agree that to designate "confidential" material covered by this  
21 agreement, the United States shall so designate, on the material itself, on a diskette cover, or in  
22 an accompanying cover letter, by using the following designation: "CONFIDENTIAL  
23 INFORMATION – SUBJECT TO PROTECTIVE AGREEMENT."

24 2. Counsel shall narrowly tailor the documents, materials, or papers that come within  
25 this order.

26 3. The failure to designate any materials as provided in this paragraph shall not  
27 constitute a waiver of any assertion that the materials are covered by this Protective Agreement

28 4. The defendant, including defendant's counsel and their personnel, agree to use

1 these materials only for the purposes of this criminal action, and agree not to disclose these  
2 materials to non-parties except as needed for the defense of this criminal action, and only if the  
3 nonparty signs this letter, or another copy of this letter, which will be subsequently provided to  
4 counsel for the United States. If defense counsel wishes to utilize the services of any non-party,  
5 including but not limited to an investigator, expert or other individual to review the protected  
6 materials in connection with the preparation of a defense, prior to receiving access to the  
7 materials such individual must sign a copy of the "Acknowledgment of Protective Order and  
8 Proper Handling of Materials Subject Thereto" attached to a copy of this Order acknowledging  
9 that:

- 10 a) he/she has reviewed the Order;
- 11 b) he/she understand its contents;
- 12 c) he/she agrees that he/she will only access the protected materials for the  
13 purposes of preparing the defense case;
- 14 d) he/she will not make any copies of any of the protected materials without  
15 further order of the Court; and
- 16 e) he/she understands that failure to abide by this Order may result in  
17 sanctions by this Court.

18 Defense counsel shall promptly file signed copies of the Order along with the signed  
19 Acknowledgment of Protective Order and Proper Handling of Materials Subject Thereto Order,  
20 ex parte and under seal. The government shall have no access to these signed copies without  
21 further order of the Court.

22 5. As applied to documents, materials, or papers filed with the court, this order shall  
23 be used sparingly to cover only those items that are clearly trade secret, come within clearly  
24 defined areas of privileges or confidentiality accepted in the federal courts, or have a compelling  
25 need for confidentiality.

26 6. Documents, material or papers submitted as exhibits to or in support of motions or  
27 for pretrial, trial or other court proceedings shall not be filed under seal except by order of the  
28 court. Documents, materials or other papers submitted as exhibits will remain as part of the

1 court record and may not be withdrawn without order of the court.

2 7. The parties agree that the procedures for use of designated confidential documents  
3 during any hearing or the trial of this matter shall be determined by the parties and the Court in  
4 advance of the hearing or trial. The parties agree to consider redacting confidential documents,  
5 request the Court to submit such documents under seal, code the documents to protect  
6 confidential information, request that any exhibit be placed under seal, or assure that all  
7 confidential information has been removed.

8 No party shall disclose designated confidential documents in open Court without prior  
9 consideration by the Court.

10 5. Within 30 days of any judgment and sentencing, defendant shall return these  
11 confidential documents and all copies, as well as notes, memoranda, summaries, or other  
12 documents containing information from the designated confidential documents, to counsel for the  
13 United States, or shall destroy these documents and certify in writing to counsel for the United  
14 States that the documents have been destroyed. If defendant believes that he must maintain the

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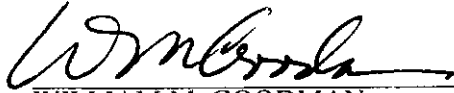
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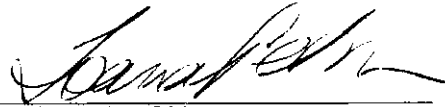
1 protected material for any reason related to appeal, defendant must seek authorization from the  
2 Court within 30 days of the sentencing and judgment in this matter.

3 SO STIPULATED

4  
5 DATED: 6/2/08

  
WILLIAM M. GOODMAN  
Attorney for Defendant Harkonen

7  
8 DATED: 6/2/08

  
IOANA PETROU  
Assistant United States Attorney

10  
11  
12 IT IS ORDERED that disclosure of the above-described discovery materials shall be  
13 restricted as set forth above and that this Order supersedes and takes the place of the Stipulated  
14 Protective Order dated 23, 2008.

15  
16 DATED:

MARILYN HALL PATEL  
United States District Court Judge

**Acknowledgment of Protective Order and Proper Handling of Materials Subject Thereto**

I \_\_\_\_\_ am employed as a(n) \_\_\_\_\_ and I am assisting \_\_\_\_\_  
\_\_\_\_\_ (attorney) in the preparation of the defense of W. Scott Harkonen.

In anticipation of reviewing materials that contain individually identifiable health information, I have reviewed the attached Order. I understand its contents. I agree that I will only access the protected materials for the purposes of preparing the defense case. I will not make any copies of any of the protected materials without further order of the Court. I understand that failure to abide by this Order may result in sanctions by this Court.